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Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures

Quality Implementing Procedure ID: OSTI-LLNL-QIP-5.0, Rev.0,Mod.0

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QA: QA

PREPARING THE QUALITY ASSURANCE PLAN AND QUALITY/TECHNICAL IMPLEMENTING PROCEDURES

Quality Implementing Procedure ID: OSTI-LLNL-QIP-5.0, Rev. 0, Mod. 0 *Effective:* 2/25/05

1. PURPOSE

This Quality Implementing Procedure (QIP) describes the initiation, content, preparation, review, approval, distribution, changes to, and rescission of the Quality Assurance Plan (QA Plan), Quality Implementing Procedures (QIPs), and Technical Implementing Procedures (TIPs) for the Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Quality Assurance (QA) Program.

2. SCOPE

This QIP applies to the activities of the Originator, Technical Reviewer(s), QA Reviewer, QA Manager, Records Coordinator, Principal Investigator (PI), the Project Manager (PM), and, when assigned, the Deputy PM (DPM), during the generation, review, or revision of the QA Plan, QIP, and TIP. The OSTI-LLNL-QA Plan (QAP) is a controlled document that provides an overview of the applicability of OSTI-LLNL-QIPs to the requirements in the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. The OSTI-LLNL-QIPs and TIPs are controlled documents that are written to describe how the QAP requirements will be implemented.

The QA Plan generally identifies in what OSTI-LLNL-QIP(s) each applicable QARD requirement is addressed; where requirements are not applicable, with justification for each inapplicability; and where exceptions to requirements have been taken, with justification for each exception.

QIPs describe specific requirements for conducting and documenting quality-affecting activities in support of science and technology tasks. OSTI-LLNL-QIPs may reference DOE/OCRWM Administrative Procedures (APs) and DOE/OCRWM Line Procedures (LPs) when direct interface is required (e.g., requesting baselined software that has been developed for the Yucca Mountain Project [YMP] from Software Configuration Management [SCM]). The contents, review, and control requirements for the QIPs shall be governed by this procedure, OSTI-LLNL-QIP-6.1, *Document Review*, and OSTI-LLNL-QIP-6.0, *Document Control.*

TIPs describe technical and scientific tasks that are repetitive and standardized. The contents, review, and control requirements for new OSTI-LLNL-TIPs shall be governed by this procedure, OSTI-LLNL-QIP-6.1 and OSTI-LLNL-QIP-6.0. The PI determines whether a new OSTI-LLNL-TIP or the use of the scientific notebook is appropriate. One-time-only or preliminary experimental tasks are documented in the scientific notebooks as part of the scientific process in accordance with OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks.* TIPs approved for use on the YMP may be used to perform tasks for the OSTI-LLNL Project provided such TIPS are referenced by TIPS, Technical Work Plans, Scientific Notebooks, etc.

Authors responsible for preparing and approving the QA Plan and QIPs/TIPs do not require training to those documents.

3. PROCEDURE

3.1 Initiating the QA Plan

The **QA Manager** shall develop the *OSTI-LLNL-QA Plan* to address the QARD requirements for the portion of the QARD which the OSTI-LLNL QA Program is implementing.

3.2 Content and Preparation of the QA Plan

The QA Plan shall contain the following sections:

1. **COVER SHEET** - with review and approval signatures of the preparer, QA Manager, and the Project Manager. The cover sheet will also contain the Revision History which will be a summary of the changes made to the QAP since the original revision was issued, including the reason for the changes.

2. **INTRODUCTION** – a summary statement of the background and purpose of the Plan. In addition, this section will provide the relationship between the OSTI-LLNL QAP and the QARD.

3. **SCOPE**– a description of the quality requirements and organizational structure responsible for implementing the quality requirements applicable to the OSTI-LLNL Project.

4. **QA POLICY STATEMENT** - a statement issued by the Project Manager to require all aspects of OSTI-LLNL work be accomplished in accordance with QAP and Implementing Procedures (TIPs, TWPs, QIPs, etc.) and that when work cannot be accomplished in accordance with implementing procedures/documents that work must be suspended until the appropriate modifications are approved and issued.

3.3 Initiating a QIP or TIP

3.3.1 Any **Staff Member** working on the OSTI-LLNL Project may propose the development of a QIP to the QA Manager or of a TIP to an appropriate PI.

3.3.2 For proposed QIPs, the **QA Manager** shall:

A. decide if a formal procedure is warranted;

B. explain the resolution to the requester; and

C. refer unresolved issues to the PM (or designee) for final resolution.

3.3.3 For proposed TIPs, the **PI** (or designee) shall:

A. decide if a formal procedure is warranted;

B. explain the resolution to the requester; and

C. refer unresolved issues to the PM (or designee) for final resolution.

Documenting the actions of Section 3.3 is only required for a new QIP (or TIP) if the requester or QA Manager (or PI) deem it necessary. However, the rationale for developing a procedure shall be documented in Section 2, "Scope," of the procedure.

3.4 Content and Preparation of QIPs and TIPs

3.4.1 For QIPs, the **QA Manager** (or designee) shall assign an Originator. The **Originator** shall obtain a unique identifying number (e.g., OSTI-LLNL-QIP-QARD Section # -sequential #) from the OSTI-LLNL **Records Coordinator** (hereafter referred to as Records Coordinator), with input from the QA Manager. The QA Manager (or designee) shall determine the level of detail and oversee the preparation and distribution of all QIPs.

3.4.2 For TIPs, the **PI** shall assign an Originator. The **Originator** shall obtain a unique identifying number (e.g., OSTI-LLNL-TIP/Task Acronym-sequential #) from the **Records Coordinator**, with input from the appropriate PI. The appropriate **PI** (or designee) shall determine the level of detail and oversee the preparation and distribution of each TIP.

3.4.3 OSTI-LLNL-QIPs and OSTI-LLNL-TIPs shall be organized into ten sections with headings as identified below. Headings that are not applicable shall be designated in the procedure as such (e.g., "None," "Not applicable"); a brief statement of non-applicability is required for documentation purposes under each heading. These ten sections are:

1. **PURPOSE** — a summary statement of the procedure objective;

2. **SCOPE** — a description of the general circumstances, organization(s) and personnel to which the procedure applies;

3. **PROCEDURE** — a step-by-step description of the work process, including prerequisites, limits, safety considerations, process parameters, technical and/or regulatory requirements, and environmental conditions. This section also includes, as appropriate, identification of quality verification and hold points, methods for ensuring that the work is performed as required, and associated activities and methods for altering the sequence of required activities.

   Applicable elements of calibration and equipment operations information contained in Vendor or Manufacturer's Technical Manuals shall be incorporated or attached to TIPs. Any changes or updates to the information contained in Vendor Technical Manuals provided by the

equipment suppliers that affect the calibration and associated equipment operations shall be included in a revision to the TIP, as applicable. All other manuals, or procedures contained in manuals may be included by reference as long as they are:

- uniquely referenced (by document number, revision, etc.),
- available at the work place,
- readily available to all potential users, and
- reviewed and submitted to the Records Processing Center (RPC) in Las Vegas;

4. **RECORDS** — a list of QA record packages or individual QA records, identified as QA Records, a list of non-QA records packages or individual records identified as Non-QA Long-Term Records, and/or individual records identified as Non-QA Short-Term Records (Three Years or Less Retention);

5. **RESPONSIBILITIES** — specific statements defining critical positions, organizations and organizational interfaces responsible or necessary for the effective implementation of the procedure;

6. **ACRONYMS AND DEFINITIONS** — a location for identifying relevant acronyms and clarifying or defining terms, to help the reader understand the content of the procedure;

7. **REFERENCES** — a list of documents, including procedures, referenced in the procedure's text;

8. **ATTACHMENTS** — a list of supplementary information, forms, figures or other materials not included in the required sections of the QIP/TIP;

9. **REVISION HISTORY** — a summary of the changes made to the procedure since the original version was issued, including the reasons for the changes; and

10. **APPROVALS** — a signature page, identifying the Originator, and confirming the acceptable review of the procedure by the proper Technical, QA, PI (for TIPs) Reviewers, and the PM, as applicable.

Each page of the procedure shall show the unique procedure identifying number, revision and modification number.

3.5 Review and Approval of the QA Plan, QIPs and TIPs,

3.5.1 During the preparation and review process, the **Originator** shall uniquely identify each draft (e.g., Draft 00A, Draft 00B, etc.) and final revision/modification number (e.g., Rev. 0, Mod. 0; Rev. 0, Mod. 1 etc.)

The **Originator** shall retain the originals of the initial draft; all subsequent formally reviewed drafts, associated review forms, applicable review criteria, and the final document per OSTI-LLNL-QIP-6.1.

3.5.2 The QA Plan shall undergo one technical review, and one QA Review, with final approval by the PM.

3.5.3 All new and revised QIPs/TIPs shall undergo at least one technical reviews and one QA review by qualified individuals, selected by the PM/DPM. For QIPs, the **QA Manager** and the **Originator** shall provide reviewer recommendations. For TIPs, the **PI** shall recommend the technical reviewers, and in consultation with the **QA Manager**, shall recommend the QA reviewer.

3.5.4 All identified reviewer(s) of the QA Plan, or QIPs/TIPs shall review the draft documents according to OSTI-LLNL-QIP-6.1. Reviewers shall use the review criteria listed in Attachment 1, Standard Review Criteria as follows:

A. For the QA Plan
- The QA Plan Review Criteria shall be assigned to all QA Plan reviewers.

B. For QIPs
- The Review Criteria for Procedures shall be assigned to QIP Technical Reviewers.
- The Review Criteria for Procedures and the QA Review Criteria shall be assigned to the QA Reviewer.

C. For TIPs
- The Review Criteria for Procedures and the Technical Review Criteria shall be assigned to the Technical Reviewers.
- The Review Criteria for Procedures and the QA Review Criteria shall be assigned to the QA Reviewer.

Additional review criteria may be assigned by the PM/DPM, as appropriate.

3.5.5 If an organization other than OSTI-LLNL will perform work under a proposed QIP or TIP or revision thereof, then the draft procedure shall be submitted to the organization for review. The **Originator** (or designee) shall provide detailed review instructions in a memorandum to the reviewing organization, including review criteria and a due date for submittal of comments.

3.5.6 The **Originator** shall complete the comment resolution, incorporate the reviewers' comments and submit the final draft document to the QA Manager (for the QA Plan and QIPs) and the PI (for TIPs) to determine

when the document should be effective and to assign the effective date to the document.

3.5.7 The QA Plan, QIP, or TIP shall be submitted to the PM for final review/approval. Any comments, other than editorial, resulting from the PM's review/approval shall be documented according to OSTI-LLNL-QIP-6.1.

3.5.8 The **Originator** shall incorporate the PM's comments (if any) into a final version of the document, add the effective date to the document header and then route the original copy to all reviewers for their approval signatures. Each responsible individual shall sign and date, in dark ink, in the appropriate signature space. The final signature shall be that of the PM. The Originator shall transmit the document to the Records Coordinator for controlled distribution per OSTI-LLNL-QIP-6.0 and submittal to the RC per OSTI-LLNL-QIP-17.0, *Records Management*.

3.5.9 Upon approval of the QA Plan, the **QA Manager** (or designee) shall submit the QA Plan to the OCRWM Office of Quality Assurance (OQA) for review and concurrence. If OQA comments require changes to the QA Plan, changes shall be incorporated by revision or modification of the controlled document, per Section 3.7.

3.6 Distributing the QA Plan, a QIP or TIP

3.6.1 The **Records Coordinator** shall update the OSTI-LLNL controlled document list, the Table of Contents for QIPs and TIPs, and provide for controlled distribution of the QA Plan and procedures to the workplace in accordance with requirements in OSTI-LLNL-QIP-6.0.

3.6.2 The controlled document recipient(s) shall make the document readily available at the workplace, use only the latest revision with all approved changes, and destroy or mark the document as "superseded" accordingly.

3.6.3 The **Records Coordinator** shall handle copies of superseded versions of such documents in a controlled manner, in accordance with OSTI-LLNL-QIP-6.0.

3.7 Making Changes to the QA Plan or an Active QIP/TIP

3.7.1 QA Plan

A. When notification is received from OQA of a QARD revision, the **QA Manager** (or designee) shall perform a QARD revision impact evaluation and determine whether changes to the QA Plan or QIPs are necessary. The **QA Manager** (or designee) shall notify the OQA,

in writing, that the review is completed, identifying the needed changes, the estimated completion date for these changes, and initiate the change process, as appropriate.

B. If the OQA review of the QA Plan results in comments requiring changes to the QA Plan, the **QA Manager** (or designee) shall initiate the change process in the same manner as the original.

3.7.2 QIPs/TIPs

If, while implementing a QIP or TIP, work cannot be performed as described without producing an undesirable result, the **Staff Members** performing the work (or the responsible PI) shall stop work. The staff members, with supervisory input, shall determine what kind of changes shall be made to the QIP or TIP prior to resuming work.

3.7.3 Types of Changes

Two types of changes can be made to the QA Plan and QIPs or TIPs: modifications, including editorial changes, and revisions. In addition to these types of changes, expedited changes can be made to TIPs.

A. Modifications

Modifications are changes to the QA Plan or a procedure that are minor or affect a limited section of the document. Editorial Changes shall be considered modifications and are limited to the following:

- grammatical or spelling corrections,
- renumbering sections that do not affect the chronological sequence of the work.
- changing the title or number of the document
- updating organizational title(s), when responsibilities remain the same.

Modifications shall be implemented by the **QA Manager** (or designee) for the QA Plan and QIPs, and the **PI** (or designee) for TIPs. Modifications shall be prepared as follows:

1. prepare draft pages for the document, including sidebars to indicate the location of the change.

2. obtain reviews of the modified sections of the document in accordance with OSTI-LLNL-QIP-6.1 as follows :

   - QA Plan: by one Technical Reviewer and a QA Reviewer,

   - the TIP: by two Technical Reviewers one of which is the PI (if the PI is not the originator), and a QA Reviewer,

- the QIP: by one Technical Reviewer and a QA Reviewer;
- Editorial Changes do not require reviews.

3. make the appropriate changes to the Revision History section of the plan or procedure, including the reasons for the changes;
4. update the "modification number" on all pages, in a sequential pattern (e.g., beginning with "0", "1", etc.);
5. obtain approval signatures on the "Approval" section of the modified Plan/QIP/TIP:
   - for Editorial Changes, The **QA Manager** shall approve QIPs and the **PI** shall approve TIPS
   - for other Modifications, the reviewers shall sign the approval page
   - the **PM** shall approve all modifications
6. issue the modified document to controlled document recipients, with instructions according to OSTI-LLNL-QIP-6.0.

The **Originator** shall assure that record packages consisting of the original signed OSTI-LLNL QA Plan/QIP/TIP, review documentation and other supporting materials are created and transmitted to the Records Coordinator for controlled distribution per OSTI-LLNL-QIP-6.0 and submittal to the RC per OSTI-LLNL-QIP-17.0, *Records Management*.

3.7.4 Revisions

Revisions to the QA Plan and active QIPs and TIPs are required following issuance of a third modification to the document, or sooner if the changes to the document are substantial. The **QA Manager** or a **PI** initiates a revision by:

A. Reviewing the historical changes to the (a) QA Plan and QIP (by the **QA Manager**), and (b) TIP (by the **PI**);

B. Assigning an **Originator**, who shall renumber all pages to indicate the new revision and modification numbers. The revision number shall be one greater than the previous revision number, and the modification number shall be reset to zero. The "Revision History" section of the new revision to the document shall also be updated, including:
   - identification of changes,
   - the reason(s) for the change(s); and

C. Completing the contents, review and approval requirements per Sections

3.2, 3.4, and 3.5, as applicable.

3.7.5 The **QA Manager** (or designee) shall submit revisions/modifications of the QA Plan to OQA for review and concurrence, as described in Section 3.5.9. In addition, any QIPs issued in response to changes to the QA Plan shall be submitted to OQA for review.

3.7.6 Expedited Change(s) to a TIP

If the responsible **PI** (or designee) determines that a modification (Section 3.7.3) or a revision (Section 3.7.4) to a TIP would cause an unreasonable delay in proceeding with the task, then an expedited change to the procedure (including documentation of deviation from the approved technical process) can be made. Such changes are subject to review, usually after the task has proceeded, and thus work performed under TIPs with expedited changes is done at risk of future invalidation.

The **Originator** shall make expedited changes to a TIP by:

A. attaching a memo with a description of the change(s) and justification, and making corresponding handwritten text change(s), to the local copy of the TIP, and/or cross referencing the changes in the scientific notebook;

B. dating and initialing the handwritten change(s); and

C. processing the change per this procedure as a modification, revision, or rescission, as soon as practical but within 90 working days. If the expedited change is found to be unacceptable, then any work performed under that expedited change is subject to an evaluation by technical review.

The **Originator** shall create a record package containing a copy of the expedited change and the resolution of the resulting review and transmit it to the Records Coordinator for maintenance in the RC.

3.8 Rescinding a QIP or TIP

3.8.1 Rescinding a QIP

Any **staff member** may suggest the rescission of a QIP to the QA Manager. The **QA Manager** (or designee) shall evaluate the suggestion and confer with the PM. If all parties are in agreement and with PM approval, the QA Manager shall rescind the procedure, and justify the action in a memo to the procedure records package. The **Records Coordinator** shall assure that the list of OSTI-LLNL controlled documents is updated accordingly and shall notify all controlled document holders to return, destroy or mark their copies of the rescinded document as "cancelled," according to OSTI-LLNL-QIP-6.0.

Upon rescission of a QIP, the QA Manager shall update the QA Plan and submit it to OQA for review and concurrence, in accordance with Section 3.5.9.

3.8.2 Rescinding a TIP

Any **staff member** may suggest the rescission of a TIP to the appropriate PI. The **PI** (or designee) shall evaluate the suggestion and confer with the QA Manager. If all parties are in agreement and with PM approval, the PI shall rescind the procedure, and justify the action in a memo to the procedure records package (with a copy to the QA Manager.)

The **Records Coordinator** shall assure that the OSTI-LLNL list of controlled documents is updated accordingly and shall notify all controlled document holders to return, destroy or mark their copies of the rescinded document as "cancelled," per OSTI-LLNL-QIP-6.0.

4. RECORDS

The records listed below shall be collected and submitted to the RC in accordance with OSTI-LLNL-QIP-17.0, as individual records or included in a records package.

4.1 QA Record

Expedited changes, revisions, modification records supporting reviews per OSTI-LLNL-QIP-6.1

Records submitted per OSTI-LLNL-QIP-6.0:
Final, approved QA Plan
QIPs/TIPs

4.2 Non-QA Long-Term Records

Reviewed drafts

4.3 Non-QA Short-Term Records (three years or less retention)

General procedure distribution memoranda (if used)

5. RESPONSIBILITIES

5.1 The **Project Manager** (PM) is responsible for the final approval of the new and revised QA Plan, QIPs and TIPs. The PM is also responsible for final approval of the rescission of the QIPs and TIPs.

5.2 The **Deputy PM** is responsible for assignment of technical and QA reviewers for the QIPs, TIPs, and revisions thereof.

5.3 The **Principal Investigator (PI)** is responsible for the preparation (or delegation thereof), review, distribution, implementation and rescission of applicable TIPs.

The PI is responsible for related training of personnel to the TIPs.

5.4 The **QA Manager** is responsible for preparing the QA Plan; for overseeing and coordinating preparation, review, approval, revision, distribution and rescission of QIPs; and for revising the QA Plan, if appropriate. The QA Manager (or designated QA Reviewer) is also responsible for the review and approval of TIPs.

5.5 **Staff Members** are responsible for suggesting the development of new QIPs, TIPs and modifications thereto. The staff members involved in the preparation or review of procedures are responsible for following this procedure, OSTI-LLNL-QIP-6.1, and turning over related documentation to the Records Coordinator for maintenance in accordance with OSTI-LLNL-QIP-17.0.

5.6 The **Records Coordinator** is responsible for assigning procedure numbers to QIPs and TIPs, providing the controlled distribution of the QA Plan, QIPs and TIPs, (and revisions/modifications thereof) in accordance with OSTI-LLNL-QIP-6.0, and for maintaining all records in the RC, in accordance with OSTI-LLNL-QIP-17.0.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

AP	OCRWM Administrative Procedure
DOE	U. S. Department of Energy
LLNL	Lawrence Livermore National Laboratory
LP	OCRWM Line Procedure
M&TE	Measuring and Test Equipment
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
OSTI	Office of Science & Technology and International
PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QAP	Quality Assurance Plan
QARD	Quality Assurance Requirements and Description
QIP	OSTI-LLNL Quality Implementing Procedure
RC	Records Center
SCM	Software Configuration Management
TIP	OSTI-LLNL Technical Implementing Procedure
YMP	Yucca Mountain Project

6.2 Definitions

Quality Implementing Procedure: Each QIP describes an aspect of the OSTI-LLNL implementation of QARD requirements or project level procedure.

Technical Implementing Procedure: Each TIP describes OSTI-LLNL technical and/or scientific tasks that are repetitive and standardized.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description (QARD)*

OSTI-LLNL-QIP-6.0, *Document Control*

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

8. ATTACHMENTS

Attachment 1 - Standard Review Criteria for Procedures

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0:
Initial Issue

10. APPROVALS

Preparer: Leigh Gouveia — Date: 2/25/05

Technical Reviewer: QINHONG HU — Date: 2/25/05

QA Reviewer: VICTOR J. BARISH JR — Date: 2/25/05

Project Manager: DAVID B. MACALEW — Date: 2/25/05

STANDARD REVIEW CRITERIA FOR PROCEDURES

QA Plan Criteria

1. Does the Plan identify where the QARD requirements are directly addressed within the organization's procedures?
2. Does the Plan identify where QARD requirements are not applicable based on scope of work?
3. Does the Plan identify where exceptions to QARD requirements have been taken and include justification for the exception?
4. Does the Plan adequately incorporate revisions to the QARD and to implementing procedures as revised?

Review Criteria for Procedures

1. Are the purpose and applicability of the procedure clearly specified?
2. Are the responsibilities clearly delineated and consistent with established OSTI-LLNL responsibility?
3. Are the requirements delineated in the procedure implementable?
4. Are the content and format of the draft procedure consistent with Section 3.2 of OSTI-LLNL-QIP-5.0?
5. Do the forms specify the minimum information required?
6. Are the forms and attachments consistent with the procedure being reviewed?
7. Does the change history adequately reflect the changes made?
8. Is the procedure compatible with other procedures?
9. Does the document include or reference appropriate acceptance criteria for determining that prescribed processes have been satisfactorily accomplished?
10. For TIPs, have controls on the electronic management of data been included, as applicable?

QA Review Criteria for Procedures

1. For QIPs, is the procedure consistent with requirements in the QARD?

2. Are specific responsibilities and authorities consistent with OCRWM policy or other applicable requirements?

3. Are terms that are defined in the QARD used in a context consistent with QARD definition?

4. Do the defined process and controls adequately, completely, accurately, and correctly address the applicable QA requirements?

5. Is the activity to which the procedure applies clearly identified?

6. Is the procedure appropriately integrated with other procedures or processes?

7. Are the applicable requirements of the source documents incorporated in to the procedure?

8. Does the procedure include or reference appropriate acceptance criteria for determining those prescribed processes have been satisfactorily accomplished?

9. Are records generated by the procedure appropriately classified?

10. Do notes contain information that augments the procedure, without containing action steps?

Technical Review Criteria for TIPs

1. Is the procedure technically adequate, correct, complete, accurate, applicable to the issue being addressed?

2. Are hold points identified?

3. Are applicable standards and criteria identified?

4. Have field and laboratory equipment been identified?

5. Are calibration requirements and methods identified?

6. Are unique materials identified?

7. Are special training/qualifications identified, if appropriate?

8. Are data recording/reduction techniques adequate?

9. Are analytical methods/techniques adequate?

10. Are precision and accuracy of Measuring and Test Equipment (M&TE) discussed?

11. Are prerequisites, special controls, and environmental conditions addressed?

12. Are the controls necessary to mitigate hazards identified?